UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): **December 9, 2020 (December 9, 2020)**

PLURISTEM THERAPEUTICS INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	**001-31392**	**98-0351734**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

MATAM Advanced Technology Park **Building No. 5** **Haifa, Israel**	**3508409**
(Address of Principal Executive Offices)	(Zip Code)

011 972 74 710 7171
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.00001 per share	PSTI	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On December 9, 2020, Pluristem Therapeutics Inc., or the registrant, held an investor and analyst call pursuant to which it shared a presentation. The presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 8.01 Other Events.

On December 9, 2020, the registrant announced that the independent Data Monitoring Committee, or DMC, of its global pivotal Phase III study of the registrant's PLX-PLD product for the treatment of critical limb ischemia, or CLI, issued its recommendation letter following an interim analysis. The clinical dataset was reviewed by the independent DMC for safety and analysis of the primary endpoint of amputation-free survival, defined as time to occurrence of major amputation of the index leg or death. Based on the review, the DMC advised that the CLI study is unlikely to meet the primary endpoint by the time of the final analysis. The DMC advised the registrant that the CLI study population has experienced a substantial low number of events (major amputation of the index leg or death), different from what is known in clinical medicine for the rate of these events in this patient population. The lower than anticipated event rate in the placebo group reduced the statistical power of the study to meet its primary endpoint. The DMC noted that PLX-PAD was well tolerated, and no significant safety concerns were raised during the study. Following the DMC's recommendation, the registrant decided to terminate the CLI study. Currently, the registrant continues to be blinded to the CLI study clinical data.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Investor and analyst call presentation, dated December 9, 2020 (furnished herewith)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PLURISTEM THERAPEUTICS INC.

By: */s/ Chen Franco-Yehuda*
Name: Chen Franco-Yehuda
Title: Chief Financial Officer

Date: December 9, 2020

Exhibit 99.1

PLURISTEM CONFERENCE CALL

December 9, 2020

Inspired by Life

Forward Looking Statements

This presentation contains express or implied forward-looking statements within the Private Securities Litigation Reform Act of 1995 and other U.S. Federal securities laws. For example, we are using forward-looking statements when we discuss that we expect topline clinical results during the calendar year 2021 with respect to our Phase III study in muscle regeneration following hip fracture, our Phase II studies in ARDS associated with COVID-19 and our Phase I study in incomplete hematopoietic recovery following HCT, our belief that we are well positioned to support the future development of these indications, our belief that our platform and technology will be a meaningful force in regenerative medicine in a variety of therapeutic areas and the expected timing of the first tranche of a loan from the European Investment Bank (EIB). These forward-looking statements and their implications are based on the current expectations of our management only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; we may encounter delays or obstacles in launching and/or successfully completing our clinical trials; our products may not be approved by regulatory agencies, our technology may not be validated as we progress further and our methods may not be accepted by the scientific community; we may be unable to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties may develop with our process; our products may wind up being more expensive than we anticipate; results in the laboratory may not translate to equally good results in real clinical settings; results of preclinical studies may not correlate with the results of human clinical trials; our patents may not be sufficient; our products may harm recipients; changes in legislation; inability to timely develop and introduce new technologies, products and applications; loss of market share and pressure on pricing resulting from competition, which could cause our actual results or performance to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, we undertake no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting us, reference is made to our reports filed from time to time with the Securities and Exchange Commission.

Critical Limb Ischemia (CLI) Interim Analysis

- The company's Phase III CLI study is unlikely to meet its primary endpoint by the time of the final analysis
- CLI study population has experienced a substantial low number of events different from what is known in literature*. The lower than anticipated event rate in the placebo group reduced the statistical power of the study to meet its primary endpoint.
- PLX-PAD was well tolerated, and no safety concerns were raised
- Currently, the Company continues to be blinded to the CLI study clinical data
- Pluristem decided to terminate the CLI study to focus on different therapeutic areas in its pipeline and expects three clinical readouts during calendar year 2021

*Reiniecke at el, 2015

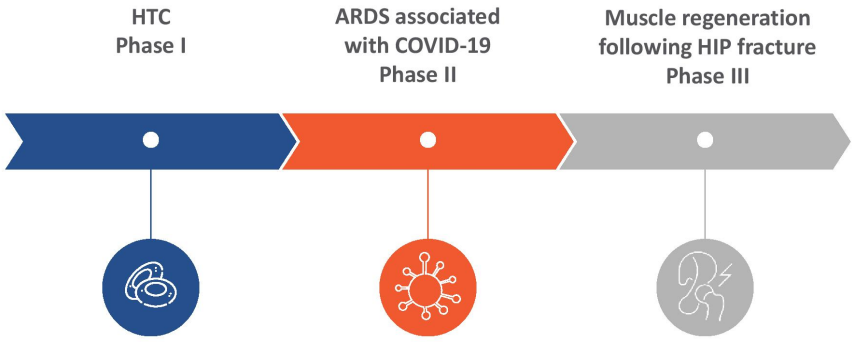
Clinical Pipeline

PRODUCT	FOCUS	INDICATION	LOCATION	FUNDING/ Partner	PRECLINICAL / PHASE I / PHASE II / PHASE III
PLX-PAD	Muscle Injuries	Muscle Regeneration following Hip Fracture	U.S., Europe, Israel		
	Inflammatory Diseases	ARDS due to COVID-19	U.S., Europe, Israel		
		Graft Versus Host Disease	Israel		
PLX-R18	Hematological Deficiencies	Acute Radiation Syndrome*	U.S.	NIH NIAID	
		Incomplete Recovery Following Bone Marrow Transplantation	U.S., Israel		

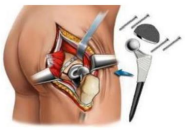
*Via FDA Animal Rule

Pluristem's One-Platform Multiple-Applications Strategy

Clinical readouts expected within the coming calendar year

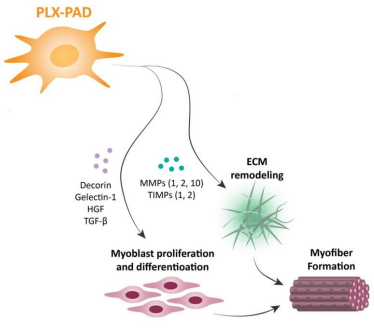


Ongoing Muscle Regeneration Following Hip Fracture - Phase III Study

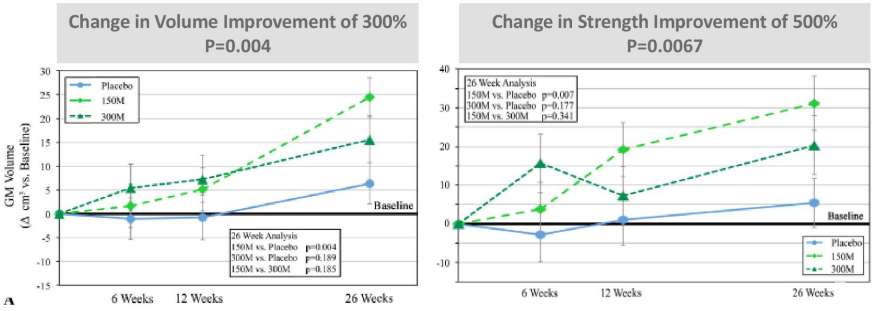


U.S., Europe & Israel (N=240) approximately 70% of the study's population enrolled

- Worldwide, the total number of hip fractures is expected to surpass **6 million** by the year 2050*
- Hip fracture often leads to serious long-term complications, including pain, functional decline and disability.** Up to 36% mortality rate after one year due to immobility associated diseases***



Phase I/II Study of PLX-PAD for Muscle Injury Following Total Hip Replacement *(N=20)*

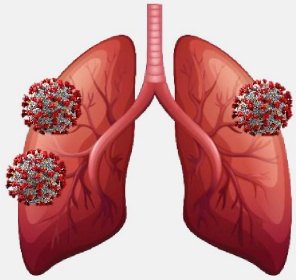


*Kannus P, Parkkari J, Sievänen H, et al. Epidemiology of hip fractures **Simran Mundi, et. al. 2014 ***Jorma Panula, et. al. 2011

Severe ARDS (Acute Respiratory Distress Syndrome) Associated with COVID-19

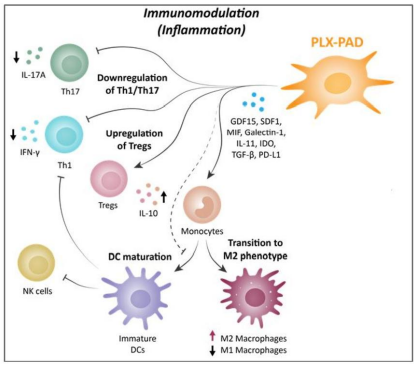
One of the most common causes of death from COVID-19

Clinical programs
- Phase II and Expanded Access Program in the U.S.
- Phase II in Europe and in Israel
- Compassionate Use in Israel



PLX-PAD cells have immunomodulatory and cytoprotective properties which may play a meaningful role in mitigating the tissue-damaging effects of COVID-19 on the lungs

Mechanism of Action



COVID-19 Data

Encouraging results from Compassionate Use Programs in the U.S. & in Israel

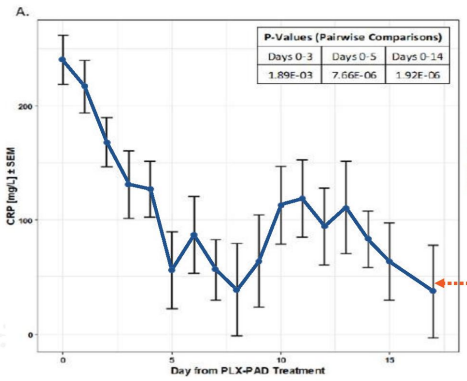
28-day follow-up for the first 8 ventilator-dependent COVID-19 patients (Reported May 2020)

87.5% Survival rate

75.0% of patients were off any mechanical ventilation

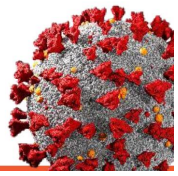
62.5% of patients were discharged alive from the hospital compared to 3.3% (38 out of 1151 patients)*

Changes in C-Reactive Protein (CRP) test evaluating liver response to inflammation**



Blood CRP decreased dramatically

in all patients following PLX-PAD treatments



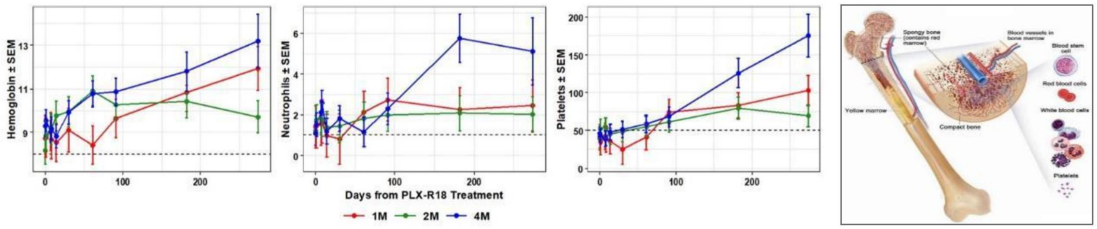
* In data published in the NY area during March-April 2020 for patients requiring mechanical ventilation and discharged alive – Richardson S et al. Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized with COVID-19 in the New York City Area. JAMA 2020. doi:10.1001/jama.2020.6775

** Barkama et al. 2020 Placenta-Derived Cell Therapy to Treat Patients with Respiratory Failure due to COVID-19 In press

Hematological Programs (PLX-R18)

Phase I – Incomplete Hematopoietic Recovery Following Hematopoietic Cell Transplantation (HCT)

- Initial results from 19 patients treated with PLX-R18 demonstrated*:
  - Significant clinical improvements in Hb, ANC, and PLT among the high-dose cohort
  - PLX-R18 was found to be safe and well-tolerated
- Topline results from the full Phase I clinical trial expected in Q1 2021 calendar year (n=21)



Day 0 – Month 9
8.74 ± 0.89 – 11.93 ± 1.01 (p=0.0025)
8.17 ± 0.65 – 9.72 ± 0.74 (p=0.037)
9.29 ± 0.50 – 13.19 ± 1.23 (p=0.0019)

Day 0 - Month 9
1.42 ± 1.05 – 2.46 ± 1.25 (p=ns)
1.22 ± 0.73 – 2.02 ± 0.87 (p=ns)
1.09 ± 0.57 – 5.13 ± 1.65 (p=0.018)

Day 0 - Month 9
41.0 ± 17.0 – 102.8 ± 20.3 (p=0.011)
39.4 ± 12.3 – 69.2 ± 14.6 (p<0.1)
45.7 ± 9.6 – 175.9 ± 27.8 (p=0.000012)

*Paper: Safety and Demonstrated Efficacy of Placenta-Derived Cell Therapy PLX-R18 in Subjects with Incomplete Hematopoietic Recovery Following Hematopoietic Cell Transplantation: A Phase I International Multi-Center Study (confex.com)

In-House Commercial-Scale Manufacturing Facility

Manufacturing Technology:

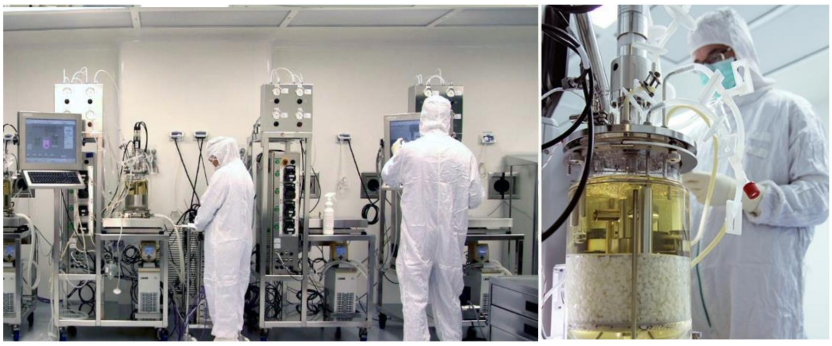
- **Patented technology platform with diverse range of applications**
- Marketing scale **3D technology** applied in all of our clinical trials
- **Cost-effective**, market-ready industrialized platform
- **Automated**, efficient and validated technology
- **Scalable** and tech-transferable technology for additional capacity
- **GMP** certified
- **No dependency on third party manufacturing subcontractor**

Manufacturing Process Approved by:

Proven:

- **Batch-to-batch consistency**
- **Comparability**
- **Off-the-shelf** biopharmaceutical: No special preparation required

State-of-the-art **3D bioreactor** cell expansion system, designed to mimic the human body



Full Vertical Solution:
From Raw Material to the Patient's Bed

Financials

Cash:
~$53 million
(as of Sept. 30, 2020)

EIB non-dilutive financing agreement: First tranche of €20 expected during H1 of 2021 calendar year*

European Investment Bank The EU bank

Extensive support by **non-dilutive** grants and **government funding**

רשות החדשנות Israel Innovation Authority

European Commission

NIH National Institutes of Health

NIAID

CRISPRIL

Solid financial position to fund the ongoing clinical studies of PLX cells in other lead indications

* https://www.sec.gov/Archives/edgar/data/1158780/000121390020026105/f10k2020ex10-20_pluristem.htm#a_016

Platform technology with advanced clinical pipeline

- Development for muscle injuries, inflammatory diseases and hematological deficiencies
- Diverse clinical pipeline with 3 clinical readouts expected in the coming year

Strong IP portfolio

Over 120 granted patents globally

Industrial scale in-house GMP manufacturing facility

- High quality cell products at a commercial scale
- Manufacturing process approved by key regulators
- Advanced cold chain logistical capabilities

Global presence

ISRAEL | U.S. | EU

Off-the-shelf placenta-derived cell products

- No blood or tissue matching required
- Young, highly potent and ethical source

Q&A

Thank you

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